January 7, 1983

Mark Novitch, M.D.
Deputy Commissioner
Food and Drug Administration (HF-2)
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Novitch:

These comments are provided with respect to the OTC decongestant phenylpropanolamine and anticipated negative agency action. Voluminous data on phenylpropanolamine was extensively reviewed by the OTC Cough/Cold Panel and the conclusion reached that the ingredient is Generally Recognized as Safe and Effective. These conclusions were published in the proposed monograph dated September 9, 1976.

Since the monograph publication, some concern about the safety of the ingredients has come to the agency's attention. It is legitimate to say, this concern has primarily come from the "look-alike" issue. There have been reports of serious side effects resulting from the consumption of excessive doses of these triple ingredient products (phenylpropanolamine, ephedrine and caffeine) which were not Category I combination products under the proposed monograph.

The agency took appropriate action (though late) in 1982 when it issued a regulation making these look-alike products new drugs. Since that time, the agency has been actively involved in eliminating the sources of supply of these look-alike products and it would be realistic to anticipate adverse reaction reports will subside in the wake of these actions.

Phenylpropanolamine is a safe and effective nasal decongestant which has been safely used for 40 years under legitimate conditions. Let's not permit past illegitimate or excessive uses of the ingredient to adversely influence the momentum in decision making processes when considering the future medically important uses and recognition of safety and efficacy.

Sincerely,

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HF-1 ✓
HF-2 ✓
HF-40 ✓
HFA-30S ✓

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